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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,880	02/19/2004	Tobin C. Island	2502187.991100	7731

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DLA PIPER RUDNICK GRAY CARY US LLP
153 TOWNSEND STREET
SUITE 800
SAN FRANCISCO, CA 94107-1907

EXAMINER

JOHNSON III, HENRY M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SR

Office Action Summary	Application No. 10/783,880	Applicant(s) ISLAND ET AL.	
	Examiner Henry M. Johnson, III	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,27-35,43-56,60,63-73,78-89,92-101 and 104-114 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,27-35,43-56,60,63-73,78-89,92-101 and 104-114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 104-114 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 104 requires a small cordless device with an LED light source operating a peak power of over 10 watts and pulse durations of from 10 milliseconds to 1 second. Peak powers of 10 to 120 watts are disclosed for laser diodes, but not for LEDs. To achieve such peak powers with LEDs, the pulse duration is typically in the nanosecond range. The disclosure does not describe how an LED (or array of LEDs) can be used to provide the required fluence at the stated pulse duration and peak power in the size required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 27-35, 43-56, 60, 63-73, 78-89, 92-101 and 104-114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 27, 43, 79, 92 and 104 are indefinite for conflicting light levels. The light exiting the device cannot be of the required fluence for treatment and eye safe. The term eye

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safe implies the light at an eye, however, an eye cannot be claimed and such an eye would not have a defined location relative to the exit aperture of a device.

Claims 46-47, 83-84, 95-96 and 108-109 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: no means is cited for maintaining the temperature of the heatsink below normal skin temperature

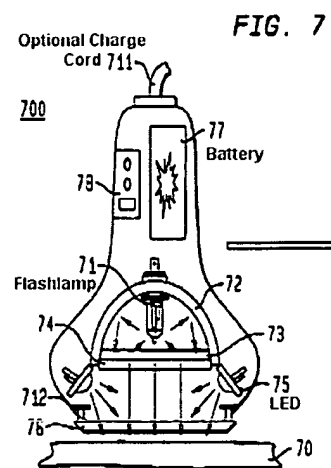
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 43, 44, 46, 48, 49, 60 and 64-65 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication US 2004/0225339 to Yaroslavsky et al. Yaroslavsky et al. teach a handheld light treatment device with a flashlamp (Fig. 7, # 71) and LEDs (Fig. 7, # 75) in a housing with a battery (Fig. 7, # 77) that may provide wavelengths from 900-1800 nanometers (abstract) at pulse durations from 1 millisecond to 100 seconds and fluences from 10 to 500 J/cm² (paragraph 0023). LEDs inherently have a divergent beam. Switching electronics (paragraph 0026) are disclosed for producing the pulses, such electronics implying an electronic



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circuit. An output window (heatsink) is disclosed (Fig. 7, # 76) at an exit aperture, the window may be cooled using various means including phase change materials and thermoelectric (paragraph 0094). A sensor is disclosed that prevents activation (paragraph 0097).

A recitation with respect to the manner in which an apparatus is intended to be employed does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Yanush, 477 F.2d 958, 177 USPQ 705 (CCPA 1973); In re Finsterwalder, 436 F.2d 1028, 168 USPQ 530 (CCPA 1971); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963); Ex parte Masham, 2 USPQ2d 1647 (BdPatApp & Inter 1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1, 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2003/0004499 to McDaniel in view of U.S. Patent 6,273,885 to Koop et al. McDaniel teaches the light treatment of living cells using arrays of LEDs at a wavelength of 810 nanometers, the LEDs covered by a diffuser (paragraph 0072). The hand held device of the present invention could be battery powered and permit treatment without the need for the patient to make an office visit. Such a device is particularly well-suited for the treatment of acne, hair removal, hair growth stimulation, vitiligo, psoriasis, stretch marks, herpes fever blisters, cuts, skin abrasions, bruises, dark under eye circles, liver spots, wrinkle removal, and other dermatological conditions (paragraph 0073). McDaniel teaches a bandwidth of from 5-20 nanometers (paragraph 0071). Using LEDs, it is inherent the peak power is less than 120 watts. McDaniel does not disclose the size and weight of the portable unit. Koop et al. teach a laser tissue treatment device capable of being handheld, the device comprising a semiconductor diode or diode array laser which emits energy and a device for surface cooling of tissue such that the energy is directed through said cooling device in contact with tissue. The diode laser operates at wavelengths between about 630 nm and 980 nm, and delivers a predetermined amount of energy in a predetermined period of time and having a predetermined spot size. A cooling device such as a sapphire plate or other active or passive cooling means is used to cool the tissue. The device is disclosed as flashlight sized with a weight of 675 grams. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the device of McDaniel with the housing of Koop et al. as both devices provide essentially the same treatment parameters and are disclosed as portable.

Providing portability to a prior art device is a design consideration within the skill of the art. In re Lindberg, 194 F.2d 732, 93 USPQ 23 (CCPA 1952).

A change in the size of a prior art device is a design consideration within the skill of the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955).

Claims 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2003/0004499 to McDaniel in view of U.S. Patent 6,273,885 to Koop et al. as applied to claims 27 and 32 above, and further in view of U.S. Patent 5,743,901 to Grove et al. McDaniel and Koop et al. are discussed above, but do not disclose specific spot sizes or peak power levels. Grove et al. disclose a medical laser device with diode lasers operating in the 700-1100 nm wavelength band to treat selected dermatological conditions by aiming the laser device to direct light energy to at least a portion of a patient's body and operating the diode laser bars to produce a pulse output, with the pulses having a duration of 1 ms to 100 ms and a fluence at the body surface of 10 to 100 J/cm² (Col. 4, lines 13-22). The peak power is disclosed as 50 watts (Col 2, line 24). The aperture opening (spot size) is disclosed as 0.8cm² (Col. 6, line 38). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the spot size and power as taught by Grove et al. in the invention of McDaniel combined with Koop et al. to provide the desired fluence on the treated area. The power and spot size are well known to the skilled artisan as controllable parameters to achieve a specific treatment.

Claims 45, 47 and 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2004/0225339 to Yaroslavsky et al. as applied to claims 43, 44 and 46 above, and further in view of in view of U.S. Patent 6,273,885 to Koop et al. Both are discussed above and use a transmissive window aperture. Koop et al. teaches the window being sapphire. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the sapphire window as taught by Koop et al. in the device of Yaroslavsky et al. as sapphire is well known for use as a radiation window material.

Claims 54-56 and 66-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2004/0225339 to Yaroslavsky et al. as applied to claim 43 above, and further in view of in view of U.S. Patent 5,743,901 to Grove et al. All have been

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previously discussed, however, Yaroslavsky et al. does not disclose specific spot sizes or peak power levels. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the spot size and power as taught by Grove et al. in the invention of Yaroslavsky et al. to provide the desired fluence on the treated area. The power and spot size are well known to the skilled artisan as controllable parameters to achieve a specific treatment.

Claims 63, 72 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2004/0225339 to Yaroslavsky et al. as applied to claim 43 above, and further in view of in view of U.S. Patent Application Publication US 2003/0004499 to McDaniel. Both have been previously discussed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the bandwidths and radiation diffusers as taught by McDaniel in the invention of Yaroslavsky et al. as the bandwidths of lasers and LED's are known to be narrow as disclosed by McDaniel and diffusing of the radiation is a well known technique to normalize the radiation.

Claims 69-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2004/0225339 to Yaroslavsky et al. as applied to claim 43 above, and further in view of in view of U.S. Patent 6,494,900 to Salansky et al. Yaroslavsky et al. is discussed above, but, while it is intuitive that a handheld laser device would not use a bulky transformer or large storage capacitor, it is not specifically stated. Salansky et al. teach a wearable laser and LED medical device with circuits to drive the radiation devices. None of the circuits in figures 6 or 7 show transformers or large capacitors. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use drive circuits without transformers or large capacitors as taught by Salansky et al. in the device of Yaroslavsky et al. to conserve power and reduce the weight.

Claim 78 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2004/0225339 to Yaroslavsky et al. as applied to claim 43 above,

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and further in view of in view of U.S. Patent 4,905,690 to Ohshiro et al. Yaroslavsky et al. is discussed above, but does not teach audible feedback. Ohshiro et al. teach a laser treatment device with a touch sensor, divergence adjustment and an alarm that provides a signal via a speaker (Col. 10, lines 21-28). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the alarm as taught by Ohshiro et al. in the device of Yaroslavsky et al. to alert an operator of an abnormal or unsafe condition.

Claims 79-85, 88-89, 92-97 and 100-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2004/0225339 to Yaroslavsky et al. in combination with Patent Application Publication US 2003/0004499 to McDaniel, U.S. Patent 5,743,901 to Grove et al. and U.S. Patent 6,273,885 to Koop et al. All have been previously discussed and disclose various parameters and components of a radiation medical device. The parameters are well known to one skilled in the art for achieving a desired treatment and therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the inventions to obtain a portable, handheld radiation device.

Claims 86-87 and 98-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2004/0225339 to Yaroslavsky et al. in combination with Patent Application Publication US 2003/0004499 to McDaniel, U.S. Patent 5,743,901 to Grove et al. and U.S. Patent 6,273,885 to Koop et al. as applied to claims 85 and 97 above, and further in view of in view of U.S. Patent 4,905,690 to Ohshiro et al. All have been previously discussed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the alarm and contact sensor as taught by Ohshiro et al. in the combined invention to improve the safety and operability of the treatment device.

Conclusion

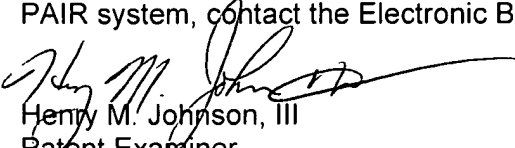
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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 5,707,403 to Grove et al. teaches a laser device with spot sizes from 0.1 to 10 cm². U.S. Patent 6,106,514 to O'Donnell, jr. discloses a device for delivery of pulsed infrared radiation with a spot size of .25 cm² and peak powers of 10-250 watts and a cooled sapphire window with a diffusing element. U.S. Patent 5,464,436 to Smith teaches a handheld laser device with an audible alarm.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Henry M. Johnson, III
Patent Examiner
Art Unit 3739